

ER/DL SPL Team Meeting

Minutes

October 13, 2010

Chair of today's meeting: Jessica Dunn Skorupski

Next scheduled meeting: October 27, 2010

Topics discussed

1. FDA cross checking R4 files against posted R3 files – Jean K..
 - They just ran into a new situation. New SPL R4 file. The file failed validation because it was cross checked against a previous R3 file. They weren't aware that FDA was cross checking.
 - The difference in the files were data values – ie different UNII codes, different types of packaging, dosage forms, etc.
 - System assumes that since you changed a key product data value, that it is really a new product.
 - Solution: contact Lonnie with an explanation, and he will have to manually load the product.
 2. When is a drug truly listed? Herb
 - There are multiple potential meanings/needs for being “listed” – import, NDC directory
 - If you put in a future date, the SPL will not get posted to the Daily Med or on the NDC directory – until that date. But the file is available to customs staff to use in managing imports.
 - NDC directory: if there is a problem with it not appearing on the NDC, send an email to the DRLS email.
 - Import: Import staff can access the files out of the eLIST system.
 - CMS: uses only those NDC codes that are on NDC directory.
 - Dragan submitted an SPL for PLAIR with date of 2020 so that the API would come into the country. They assumed that it was drug listed because customs let the API into the country.
 - PLAIR are being managed in 2 ways
 - One way: send in SPL to drug list with a future market start date.
 - Second way: tell them you will drug list at approval.
 3. PLAIR – Any experience for sNDA (new strength)? – Beth M.
 - Goal: rapid launch?
 - Opinion: PLAIR is there for any product that has an imminent NDA approval.
 4. Sponsor Submitted a couple of SPL files with no exceptions. The old files were removed but new files didn't take their place. They went directly to the archive.
 - Others have had similar problems. Contact NLM and explain the problem. They have been able to resolve it within a couple of days.
 5. Marcia announced that Lonnie and Import staff will conduct a Q&A session at their next OTC meeting
 - Nov 8, 1 pm. See wiki for telephone call in information.
 - Please send questions in advance to Marcia, so that she can forward them to Lonnie.
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In Process topics:

- Arranging a discussion at a future meeting with someone at CMS -- to discuss how CMS interacts with drug listing (Pat and Terry)
- Process for export products (Pat/Jean)
- Rationale for why it is difficult to have R3s removed manually from Daily Med (Howard/Jean/Pat)
- Communicating with FDA about validation errors – that result in issues with import, not being able to be compliant with instructions in approval letters, etc. (Warren, Jean, Dragan, and Jessica)
- Create space on wiki to collect questions for future discussions with FDA: DRLS and SPL. (Pat)